UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: **Coumaphos**. Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996.
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Background:

This memorandum constitutes the revised dietary and occupational risk assessment update for the organophosphorus acaricide coumaphos. This assessment has been revised to reflect comments received during Phase 4 of the TRAC public participation process. Changes from the previous risk assessment (C. Jarvis memo, 07/09/99, D257482) include the incorporation of monitoring data from the USDA's Pesticide Data Program (PDP) for the dietary assessment, refined percent livestock treated information, the removal of sheep and goat from both the dietary and occupational assessments, and the removal of the wettable powder and spray foam uses from the occupational assessment. There have also been minor changes made to the use information and to the calculated drinking water levels of comparison (DWLOCs). There are no changes to the toxicology section.

Attachments include the revised Dietary Exposure report (S. Mason and C. Jarvis memo, 01/13/00, D262058) and the revised Occupational Exposure Assessment (R. Sandvig memo, 12/28/99, D262059).

1.0 Executive Summary

Coumaphos, an organophosphorus acaricide, is applied directly to livestock animals for the control of arthropod pests. Registered primarily by Bayer Corporation, the solid technical is 96 percent active ingredient (ai). Other formulations include a dust formulation intermediate (25 percent ai), a dust (1 percent ai), an emulsifiable concentrate (6.15 and 11.6 percent ai), and a flowable concentrate (42 percent ai). The spray foam use of coumaphos was canceled effective July 29, 1999. The 25 percent wettable powder formulation will be canceled effective January 31, 2000. Since the Agency does not anticipate a withdrawal of the request for cancellation of the wettable powder formulation, it has been excluded from this risk assessment. Coumaphos may be applied using a high or low pressure hand wand, dip vats, mechanical dusters, shaker cans, dust bags, and back oilers/rubbers. There are no registered uses of coumaphos on agricultural crops or in/around residences.

The critical toxic endpoints selected for risk assessment are based primarily on red blood cell, brain, and plasma cholinesterase inhibition (ChEI). Coumaphos is not carcinogenic or mutagenic. Dermal and inhalation absorption are assumed to be 100%.

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for inter- and intraspecies variation. An extra UF of 3 was applied to the acute dietary risk assessment and the short- and intermediate-term inhalation assessments to account for the lack of a no observed adverse effect level (NOAEL). The FQPA Safety Factor (as required by the Food Quality Protection Act of August 6, 1996) was reduced to 1X for the dietary risk assessment. A Margin of Exposure (MOE)[1] of $100 is considered to be below the Agency's level of concern for dermal exposure. A MOE of $300 is considered to be below the Agency's level of concern for inhalation exposure.

The acute and chronic dietary risk assessments for coumaphos are highly refined (Tier 3) analyses that incorporate percent livestock treated information, anticipated residue values, and monitoring data from the U.S. Department of Agriculture's (USDA's) Pesticide Data Program (PDP). The acute dietary analysis indicates no risk of concern for any population subgroup, with an acute dietary risk estimate of 22% of the Population Adjusted Dose (PAD)[2] for the highest exposed population subgroup (all infants < 1 year) at the 99.9th percentile. The chronic dietary risk estimate is 13% of the PAD for the highest

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[1] $\text{MOE} = \frac{\text{NOAEL(mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$

[2] $\text{PAD} = \text{Population Adjusted Dose} = \frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

exposed population subgroup (children 1-6 years old). Calculated risks are based on a revised acute PAD of 0.007 mg/kg/day and a revised chronic PAD of 0.0003 mg/kg/day.

Potential exposures from coumaphos residues in drinking water were assessed using Tier 1 modeling techniques (GENEEC and SCI-GROW). Acute residues of coumaphos in drinking water do not result in an unacceptable contribution to dietary exposure. Chronic residues of coumaphos in drinking water exceed the Agency's calculated drinking water levels of comparison (DWLOCs) for the U.S. general population, children 1-6, and females (13-50).

Based on use patterns of coumaphos, nine major exposure scenarios were identified: (1a) mixing/loading liquids for high pressure hand wand; (1b) mixing/loading liquids for hydraulic type dip vats; (1c) mixing/loading liquids for swim type dip vats; (1d) mixing/loading liquids for back rubber/oilers; (2) loading dust into bags; (3) applying liquids with a high pressure hand wand; (4) applying dusts with a shaker can; (5) mixing/loading/applying liquids for low pressure hand wand; and (6) loading/applying dusts with a mechanical duster.

Short- and intermediate-term dermal and inhalation endpoints were based on cholinesterase inhibition; therefore, it is appropriate to combine the dermal and inhalation MOEs. Since the dermal and inhalation target MOEs are different (100 and 300, respectively) an Aggregate Risk Index (ARI)[3] was calculated, as opposed to a total MOE. **To be acceptable, the ARI must be equal to, or greater than, one.** For scenarios where there were no inhalation exposure data, the dermal and inhalation MOEs were not aggregated, and the target MOE remains 100.

Calculations of risk based on combined dermal and inhalation exposure indicate that the ARIs are **more than 1** or that the dermal only MOEs are **more than 100** with maximum risk reduction measures for all occupational exposure scenarios listed above **except** for the following: applying liquids with a high pressure hand wand at the application rate for cattle and swine at the use rate of 1000 gallons/day; applying dusts with a shaker can at the rate for cattle, horses, and swine bedding; and applying dusts with a mechanical duster at the rate for cattle, horses, and swine bedding.

The Agency has determined that there is likely to be minimal post-application exposure to people contacting treated animals immediately after application is complete. No exposure data are available to assess risk from such contact. The Agency has determined that the amount of exposure is likely to be substantially lower than exposure to handlers; therefore, post-application exposure was not assessed.

As mandated by the FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA), the Agency must consider total aggregate exposure from food, drinking water, and residential sources of exposure to coumaphos. Since coumaphos has no registered residential uses, this aggregate assessment will only consider exposure to coumaphos from food and drinking water. Acute exposure

[3] $ARI = 1/[(1/(\text{Dermal MOE}_{calculated}/\text{Dermal MOE}_{acceptable})) + (1/(\text{Inhalation MOE}_{calculated}/\text{Inhalation MOE}_{acceptable}))]$

through food and drinking water are below the Agency's level of concern (<100% aPAD). Therefore, the Agency concludes with reasonable certainty that residues of coumaphos in drinking water, when considered along with exposure from dietary (food) sources, would not result in an unacceptable acute aggregate human health risk estimate.

Chronic dietary (food) risk estimates are below the Agency's level of concern; however, chronic exposure to coumaphos residues in drinking water exceed the Agency's level of concern. Therefore, aggregating chronic drinking water exposure with chronic food exposure would only further exceed the Agency's level of concern.

The Agency is in the process of formulating guidance for conducting cumulative risk assessments. When the guidance is finalized, coumaphos and other ChE-inhibiting compounds (carbamates and organophosphates) will be revisited to assess the cumulative effects of exposure to multiple cholinesterase-inhibiting compounds.

2.0 Hazard Identification

2.1 Hazard Profile

The toxicology database for coumaphos is complete with the submission of the acute and subchronic neurotoxicity studies in the rat. In summary, coumaphos is highly acutely toxic via the oral and inhalation routes of exposure (toxicity categories I and II, respectively), and moderately toxic via the dermal route of exposure (toxicity category III). Coumaphos is not a dermal sensitizer or a dermal irritant.

The critical toxic endpoints selected for risk assessment are based primarily on red blood cell, brain, and plasma cholinesterase inhibition. Coumaphos is classified as a Group E chemical, indicating that it is "Not Likely" to be carcinogenic in humans via relevant routes of exposure. This classification is based on adequate studies in two animal species. No evidence of mutagenicity was seen in any study.

Dermal absorption is estimated to be 100%. This estimate is based on the observation that erythrocyte cholinesterase inhibition is observed in both oral and dermal rat studies at similar dose levels. Inhalation absorption is also assumed to be 100%.

2.2 FQPA Considerations

On September 8, 1997, the Hazard Identification Assessment Review Committee (HIARC) met to evaluate the toxicology data base of coumaphos with special consideration for the developmental, reproductive, and neurotoxicity data. These data were re-evaluated in order to address the sensitivity of infants and children from exposure to coumaphos, as required by the FQPA. The FQPA requirement was not addressed in the reregistration eligibility document dated April 21, 1995.

Developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity in young rats or rabbits following pre- or postnatal exposure to coumaphos, and comparable NOAELs were established for adults and offspring. The results of the two-generation reproduction study in rats showed no increased sensitivity in pups over adults. Based upon a weight-of-the-evidence consideration of the data base, the HIARC Committee determined that a developmental neurotoxicity study in rats is not required. However, the lack of acute and subchronic neurotoxicity studies was viewed as a data gap. As a result, the FQPA Safety Factor Committee determined that the 10X factor to account for enhanced sensitivity of infants and children should be reduced to 3X.

On May 11, 1999, the HIARC re-visited coumaphos in order to evaluate the acute and subchronic neurotoxicity studies in the rat. These studies were found to be acceptable and meet guideline requirements. Data gaps for acute and subchronic neurotoxicity studies in the rat have been adequately fulfilled. The FQPA Safety Factor Committee met on May 17, 1999 to re-evaluate the hazard and exposure data for coumaphos, and recommended that the FQPA Safety Factor be reduced to 1X in assessing the risk posed by coumaphos. The Committee concluded that the safety factor could be reduced to 1X for the following reasons:

- The toxicology database is adequate for coumaphos (the previous data gap has been fulfilled)
- There is no indication of increased susceptibility in rats or rabbits to coumaphos. In the developmental and reproductive toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity
- The HIARC determined that a developmental neurotoxicity study in rats is not required
- The dietary exposure assessment does not underestimate the potential exposure to infants and children from residues in food. No exposure to infants and children from residential sources is expected

2.3 Endpoint Selection

Table 1 lists the endpoints selected for risk assessment purposes. The acute neurotoxicity study used for the acute dietary risk assessment is a more appropriate exposure scenario than the 13-week dietary study in rats, which showed effects (red blood cell cholinesterase inhibition) only after 21 days of dosing. The acute neurotoxicity study showed effects after a single oral (gavage) dose (N. Paquette memo, 05/12/99).

For short-term dermal risk assessment purposes, the toxicity endpoint from the 5-day dermal toxicity study (NOAEL = 5.0 mg/kg) in the rat replaces the toxicity endpoint from the 21-day dermal toxicity study in the rat (0.5 mg/kg). Since workers will be exposed to coumaphos for less than 21 days for

some of the use-patterns and potential exposure scenarios associated with coumaphos, a shorter-term exposure dermal toxicity study is more appropriate for assessing worker risk.

The 5-day dermal toxicity study better characterizes the shape of the dose response for the critical effect (plasma, RBC, and brain ChE inhibition) than the 2-day dermal study (NOAEL = 20 mg/kg). Overall, there is a higher level of confidence in the results from the 5-day dermal study. Support for the NOAEL comes from another 5-day dose range finding dermal study in which RBC and plasma cholinesterase was inhibited at all doses tested in female rats (lowest dose tested was 10 mg/kg). In addition, the toxicity effect from the 2-day study will underestimate the worker risk because short-term exposure is defined as exposure to a pesticide from one to seven days.

Since the HED Safety Factor Committee reduced the FQPA safety factor to 1X, the acute and chronic reference doses (RfDs) are identical to the Population Adjusted Dose (PAD) for the acute and chronic dietary endpoints.

Table 1: Endpoints selected for risk assessment purposes

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	LOAEL= 2.0 UF = 300	Plasma ChE inhibition in females and RBC ChE Inhibition in both male and female rats	Acute Oral Neurotoxicity in Rats
	Acute RfD (PAD) = 0.007 mg/kg/day		
Chronic Dietary	NOAEL=0.025 UF = 100	Plasma and RBC ChE Inhibition in both male and female dogs	Chronic Toxicity -Dog
	Chronic RfD (PAD) = 0.0003 mg/kg/day		
Short-Term (Dermal)	NOAEL=5.0 UF = 100	Brain ChE Inhibition in female rats	5-Day Dermal Study in Female Rats
Intermediate-Term (Dermal)	NOAEL=0.5 UF = 100	RBC ChE Inhibition in female rats	21-Day Dermal Study in Rats
Long-Term (Dermal)	None	The use pattern and exposure scenario does not indicate a need for long term risk assessment	
Short-Term (Inhalation)[4]	Oral LOAEL= 2.0 UF = 300	Plasma ChE Inhibition in females and RBC ChE Inhibition in males and female rats	Acute Neurotoxicity Study in Rats

[4]Oral values were selected; therefore, route-to-route extrapolation must be used (assume 100% inhalation absorption).

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Intermediate-Term (Inhalation)[2]	Oral LOAEL = 0.2 UF = 300	RBC ChE Inhibition in rats	13-Week Dietary Study in Rats
Long Term (Inhalation)[2]	None	The use pattern and exposure scenario does not indicate a need for long term risk assessment	

3.0 Exposure Characterization

3.1 Summary of Registered Uses

Coumaphos [0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2*H*-1-benzopyran-7-yl) phosphorothioate] is an organophosphorus acaricide registered primarily by Bayer Corporation for direct application to dairy cattle, beef cattle, horses, and swine for the control of arthropod pests (including ticks, scabie mites, lice, face flies, horn flies, fly larvae, fleece worms, screw worms, and cattle grubs). Coumaphos can be applied with the following equipment: high and low pressure hand wands, dip vats, mechanical dusters, shaker cans, dust bags, and back oilers/rubbers. The maximum label application rates range from 0.005 to 0.025 lbs. ai per gallon for sprays or dips, 0.076 lbs. ai per gallon of oil for backrubbers, 0.000625 to 0.013 lbs. ai per animal for dust application, and 0.042 lbs. ai per 1000 square feet of swine bedding treatment. The majority of coumaphos is used on beef cattle.

Technical coumaphos contains 96% ai; formulations include a dust formulation intermediate (25 percent ai), a dust (1 percent ai), an emulsifiable concentrate (6.15 and 11.6 percent ai), and a flowable concentrate (42 percent ai). There are no registered uses of coumaphos on agricultural crops or in/around residences.

3.2 Dietary Exposure

Tolerances have been established for the combined residues of coumaphos and its oxygen analog (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) in meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep, and in milk and eggs. [*Source: 40 CFR §180.189*]. Tolerances are set at 1.0 ppm in livestock tissues, 0.5 ppm in milk-fat residues, and 0.1 ppm in eggs. Although tolerances are still listed in the most recent CFR (revised July 1, 1998) for sheep, goats, and poultry (1.0 ppm) and eggs (0.1 ppm), the use of coumaphos on poultry (eggs) has been canceled and the use of coumaphos on goat and sheep will be revoked effective January 31, 2000. Therefore, these commodities are not included in the dietary risk analysis.

A tolerance reassessment was conducted in 1995 (J. Redden memo, 4/21/95). No changes to the established milk, sheep, cattle, horse, goat, and hog tolerances were required at that time.

Anticipated residue values (ARs) were calculated from field trial data for estimation of both acute and chronic dietary exposure, with the exception of milk (M. Metzger memo, 7/18/89). The residue values used for milk are from the USDA's PDP 1997 and 1998 monitoring data which show no detectable residues in milk out of 750 samples tested. The residue data studies continue to be acceptable and the AR values are still considered appropriate for dietary risk assessment purposes. An exception is the chronic anticipated residue value for beef fat, which has been revised to 0.072 ppm from 0.15 ppm (C. Olinger memo, 3/7/95, D211656).

In the HED RED Chapter for coumaphos, dated 4/21/95, storage stability data for animal tissue and milk were listed as outstanding. CBRS (Chemistry Branch Reregistration Support) has since determined that no additional animal tissue and milk storage stability data are required (C. Olinger memo, 8/9/95). The HED RED Chapter for coumaphos also stated that residues of coumaphos *per se* were found in cattle fat from the metabolism study at levels up to 2.5 ppm, when treated at an application rate which is less than the maximum rate for the ready-to-use, pour-on formulation. The registrant was asked to provide an explanation for the discrepancy between residue levels found in the dermal metabolism study and the magnitude of the residue studies. In a C. Olinger memo dated February 6, 1996, this discrepancy was attributed to application methods used in the metabolism study that were not typical of field use. The sampling of tissues in the metabolism study was not representative of typical slaughter practices which would likely involve considerable blending of the fat throughout the animal or with meat. The registrant adequately addressed CBRS concerns.

The USDA Food Safety and Inspection Service (FSIS) data from 1993-1997 showed that residues of coumaphos were found in beef fat, horse fat, and veal fat. In some cases, the residue levels (1.06 ppm-1.62 ppm) exceeded the established tolerance level of 1 ppm. However, the majority of the samples analyzed showed no detectable levels of coumaphos: 4 detects out of 4,500 beef fat samples (2 of which were above tolerance), and 14 detects out of 2,063 horse fat samples (4 of which were above tolerance). In a C. Olinger memo dated 9/26/95, it is stated that Bayer does not believe that the over-tolerance residues were a result of the U.S. Department of Agriculture's (USDA) treatment program. USDA's treatment program involves mostly dipping cattle in a coumaphos solution (0.3%), slaughtering them between one and six days after treatment, and analyzing samples of renal fat for residues of coumaphos. The treatment history prior to the USDA treatment is unknown. Furthermore, it is expected that residues of coumaphos would be reduced or removed through normal food preparation or processing, such as cooking meats or milk pasteurization (S. DeVito memo, 11/23/98).

3.3 Drinking Water Exposure

The Agency has calculated acute and chronic drinking water levels of comparison (DWLOCs) for exposure from coumaphos and its degradate coumaphoxon in surface and ground water. A DWLOC is the concentration of a pesticide in drinking water that is acceptable as a theoretical upper limit, in light of total aggregate exposure to the pesticide from food, water, and residential sources. Calculated DWLOCs are compared to the estimated environmental concentrations of a pesticide in drinking water

(EECs), provided by the Environmental Fate and Effects Division (EFED). If the estimated concentrations of coumaphos in drinking water are less than the Agency's levels of concern for drinking water (i.e., if the EEC < DWLOC), exposure from coumaphos in drinking water is not a risk of concern.

EFED used GENEEC as a Tier 1 screening-level model to provide an upper-bound estimate of pesticide concentration in surface water for comparison to the DWLOCs. GENEEC is a mechanistic model that represents a worst-case runoff scenario for pesticides in surface water. SCI-GROW was used as a Tier 1 screening-level model to provide an upper-bound estimate of pesticide concentration in ground water for comparison to the DWLOCs. SCI-GROW is an empirical model based on field data from prospective ground water studies. EFED does not have a model for estimating Tier 2 ground water concentrations for dietary risk assessment.

The acute and chronic DWLOCs for surface and ground water are shown in Table 2 below:

Table 2: Acute and chronic DWLOCs for surface and ground water

Acute Surface and Ground Water						
Population	**GENEEC (Fg/L)**	**SCIGROW (Fg/L)**	**aPAD (mg/kg/d)**	**Acute Food Exposure (mg/kg/d)**	**Acute Water Exposure (mg/kg/d)**	**$DWLOC_{acute}$ (Fg/L)**
U.S. Population	2.2	17	0.007	0.000618	0.006382	220
Females (13-50)	2.2	17	0.007	0.000331	0.006669	200
Infants (<1 year)	2.2	17	0.007	0.001559	0.005441	54
Chronic Surface and Ground Water						
Population	**GENEEC (Fg/L)**	**SCIGROW (Fg/L)**	**cPAD (mg/kg/d)**	**Chronic Food Exposure (mg/kg/d)**	**Chronic Water Exposure (mg/kg/d)**	**$DWLOC_{chronic}$ (Fg/L)**
U.S. Population	0.53[5]	17	0.0003	0.000013	0.000287	10
Children (1-6)	0.53	17	0.0003	0.000033	0.000267	2.7
Females (13-50)	0.53	17	0.0003	0.000009	0.000291	8.7

The maximum (acute) EECs in surface and ground water are less than OPP's levels of comparison for exposure from coumaphos in drinking water. Acute exposure from coumaphos in drinking water (surface and ground water) is not a risk of concern.

[5]The GENEEC model estimated 56-day (average) concentration can be divided by a factor of 3 prior to comparison with the $DWLOC_{chronic}$. In this case, (1.6 Fg/L) / 3 = 0.53 Fg/L.

The average (chronic) EECs in surface water are less than OPP's levels of comparison for exposure from coumaphos in drinking water; however, average (chronic) EECs in ground water are greater than OPP's levels of comparison for the U.S. general population, children 1-6, and females 13-50. Since EFED does not have a model for estimating Tier 2 ground water concentrations, no further refinements can be made.

Limitations to, and uncertainties accompanying, the drinking water data include a lack of acceptable environmental fate data for the parent coumaphos and its degradate, a lack of information on the concentration of degradation products in the bioremediated coumaphos solution, and a lack of information regarding the land application rate of bioremediated coumaphos and coumaphoxon from cattle dips.

4.0 Non-Dietary Exposure

4.1 Occupational Exposure

The Agency has determined that there are potential exposures via the dermal and inhalation routes of exposure to mixers, loaders, applicators, and other handlers during usual use-patterns associated with coumaphos. Based on use patterns of coumaphos, nine major exposure scenarios were identified: (1a) mixing/loading liquids for high pressure hand wand; (1b) mixing/loading liquids for hydraulic type dip vats; (1c) mixing/loading liquids for swim type dip vats; (1d) mixing/loading liquids for back rubber/oilers; (2) loading dust into bags; (3) applying liquids with a high pressure hand wand; (4) applying dusts with a shaker can; (5) mixing/loading/applying liquids for low pressure hand wand; and (6) loading/applying dusts with a mechanical duster. No data are available to assess exposure to dip vat applicators.

All exposure scenarios, except for mixing/loading and applying liquids for the dip vat use on cattle, are short-term exposure duration only (less than seven days). Most of the non-dip vat application of coumaphos is done by a farmer to his own animals, when arthropod pests become a problem. Mixing/loading and applying liquids for the cattle dip vat use is considered an intermediate-term exposure scenario (seven days to several months), since the quarantine areas located along the Texas/Mexican border are staffed on a continual basis, as opposed to a farmer just dipping the animals on his farm.

Mixing/loading and applying liquids for cattle dip vat use may not be considered a chronic exposure since the USDA workers dip only the local U.S. cattle and are removed from dipping operations if their cholinesterase levels reach a level of concern. Since there is no quantitative data, such as the number of cattle dipped per day, the number of days dipping takes place, etc. to determine whether there is a chronic exposure to dip vat workers in the quarantine area, the Agency requests more information on quarantine dipping practices to clarify the duration of exposure. The routes of exposure for all exposure scenarios are dermal and inhalation.

Chemical-specific data for assessing human exposure during pesticide handling activities were not submitted to the Agency in support of the reregistration of coumaphos. It is the policy of the Agency to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available. PHED is a software system consisting of two parts: a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. In general, there is high confidence in the PHED data used to assess exposure from mixing/loading liquid formulations; low confidence in the data used to assess exposure from applying liquids with a high pressure hand wand, and low to medium confidence in the data used to assess exposure from mixing/loading/applying liquids with a low pressure hand wand.

General assumptions used in the occupational exposure assessment include an average body weight of an adult handler of 70 kg and an average work day interval of 8 hours. Calculations of handler scenarios are completed using the application rates on current labels. PHED data from mixing/loading liquids for high pressure hand wands were used for the mixing/loading of liquids for dip vats and for the mixing/loading of back rubbers/oilers. A person mixing/loading for a hydraulic type dip vat is assumed to handle a total of 1,800 gallons/day for short-term uses and 450 gallons/day for intermediate-term uses. A person mixing/loading for a swim type dip vat is assumed to handle a total of 4,000 gallons/day for the short-term uses and 1,000 gallons/day for intermediate-term uses.

Coumaphos exposure to dust applicators using a mechanical duster or shaker can was assessed using a home gardener study. Since the use pattern of this study does not reflect the actual use pattern for coumaphos animal dusting, this study is considered for informational purposes only. The Agency requests data on the actual use of coumaphos dust on animals. A complete review of the home gardener study can be found in the attached Occupational Exposure Assessment chapter (R. Sandvig memo, 12/28/99; D262059).

4.2 Occupational Post-Application

No registered uses of coumaphos fall under the Worker Protection Standard (WPS). EPA has established the following for all non-WPS occupational uses of coumaphos end-use products: "Do not contact treated animals until sprays have dried and dusts have settled on the coat."

The Agency has determined that there is likely to be minimal exposure to people contacting treated animals immediately after application is complete. No exposure data are available to assess risk from such contact. The Agency has determined that the amount of exposure is likely to be substantially lower than the exposure to handlers, since coumaphos is applied directly to livestock; therefore, post-

application exposure was not assessed.

4.3 Residential

Coumaphos is not intended for use in/around residences; therefore, a residential exposure assessment was not conducted.

5.0 Risk Assessment/Characterization

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for inter- and intraspecies variation. An extra UF of 3 was applied to the acute dietary risk assessment and the short- and intermediate-term inhalation assessments for lack of a NOAEL, for a total UF of 300. The FQPA safety factor was reduced to 1X.

Both short- and intermediate-term dermal and inhalation endpoints were based on cholinesterase inhibition; therefore, it is appropriate to combine the dermal and inhalation MOEs. Since the dermal and inhalation target MOEs are different (100 and 300, respectively) an ARI was calculated, as opposed to a total MOE. To be acceptable, the ARI must be equal to, or greater than, one. For scenarios where there were no inhalation data, the dermal and inhalation MOEs were not aggregated, and the target MOE remains 100.

5.1 Dietary

DEEM™ (Dietary Exposure Evaluation Model), based on food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CFSII) from 1989-92, was used to estimate acute and chronic dietary exposure to coumaphos. DEEM™, which replaces DRES (used in the dietary exposure assessment for the 1996 Coumaphos RED), estimates exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. The DEEM™ default concentration factors were used in both the acute and chronic analyses. A summary of the residue information considered in the acute and chronic dietary analyses is included in the attached Revised Acute and Chronic Dietary Exposure and Risk Analysis memo (C. Jarvis and S. Mason memo, 01/13/00).

Acute risk: The acute analysis for coumaphos is a highly refined (Tier 3 Monte-Carlo) estimate of dietary exposure, incorporating anticipated residues (M. Metzger memo, 7/18/89), percent livestock treated information, and monitoring data from the USDA PDP program. The percent of the acute PAD utilized for the highest exposed population subgroup (infants <1 year) at the 99.9th percentile is 22%. Based on calculated risk estimates, the acute dietary risks associated with the use of coumaphos do not exceed the acute PAD for any of the DEEM™ population subgroups. Acute dietary risk estimates are shown below in Table 3.

Table 3: Acute dietary risk estimates

Population	(95th Percentile)		(99th Percentile)		(99.9th Percentile)	
	Exposure mg/kg/day	% aPAD	Exposure mg/kg/day	% aPAD	Exposure mg/kg/day	% aPAD
U.S. Population	0.000067	1%	0.000220	3%	0.000618	9%
All Infants (<1 year)	0.000046	1%	0.000241	3%	**0.001559**	**22%**
Children 1-6 years	0.000195	3%	0.000563	8%	0.001151	16%
Children 7-12 years	0.000123	2%	0.000322	5%	0.000626	9%
Females 13-50 years	0.000050	1%	0.000155	2%	0.000331	5%

Chronic risk: The chronic analysis for coumaphos is a refined estimate of dietary exposure, incorporating anticipated residues (M. Metzger memo, 7/18/89), percent livestock treated information, and PDP monitoring data.

Based on calculated risk estimates, the chronic dietary risks associated with the use of coumaphos do not exceed the chronic PAD for any of the DEEM™ population subgroups. The percent of the chronic PAD utilized for children 1-6 years old (the highest exposed population subgroup) is 13%. Chronic dietary risk estimates are shown below in Table 4.

Table 4: Chronic dietary risk estimates

Population	Exposure	% Chronic PAD
U.S. Population	0.000013	5%
All Infants (<1 year)	0.000011	4%
Children 1-6 years	**0.000033**	**13%**
Children 7-12 years	0.000022	9%
Females 13-50 years	0.000009	4%

5.1.1 Total Dietary (Aggregate)

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require that for establishing a pesticide tolerance "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, and residential uses of a pesticide. There are no residential uses of coumaphos; therefore, only exposure from food and drinking water will be considered in the aggregate risk assessment.

Acute Aggregate

The contribution of food alone to aggregate acute risk represents 22% of the aPAD for the highest exposed population subgroup (children 1-6), leaving 78% of the aPAD available for exposure through drinking water. The estimated maximum peak concentrations of coumaphos in surface water (2.213 Fg/L) and ground water (17.202 Fg/L) are below the Agency's levels of comparison for exposure from coumaphos in drinking water as a contribution to aggregate acute dietary risk.

Based on the available information, the Agency concludes with reasonable certainty that residues of coumaphos in drinking water, when considered along with exposures from food uses, would not result in an unacceptable acute aggregate human health risk at this time.

Chronic Aggregate

The contribution of food alone to aggregate chronic risk represents 13% of the cPAD for the highest exposed population subgroup (children 1-6), leaving 87% of the cPAD available for exposure through drinking water. The estimated total coumaphos residue concentration in ground water used as drinking water (17.202 Fg/L) exceeds the Agency's level of comparison for exposure from coumaphos in drinking water as a contribution to aggregate chronic dietary risk.

However, SCI-GROW is a conservative screening model that provides an upper-bound concentration estimate of coumaphos in ground water, and uses the highest labeled application rate for coumaphos to provide a worst-case estimate. Monitoring data would help to refine the risk estimates.

Uncertainties associated with EFED's Tier 1 drinking water assessment include a lack of acceptable environmental fate data for coumaphos and its degradate coumaphoxon (as a conservative estimate, it is assumed that coumaphoxon is persistent and highly mobile); a lack of information regarding the land application rates of coumaphos and coumaphoxon in bioremediated cattle dips; and a lack of information on the concentration of degradation products in the bioremediated coumaphos solution.

5.2 Occupational

The short-term dermal and inhalation NOAELs were both based on cholinesterase inhibition; therefore, the MOEs were combined to identify a total short-term MOE, **except** when there was no inhalation data (which occurred when studies lacking inhalation data were used, i.e. a shaker can). The

intermediate-term dermal and inhalation NOAELs were also based on identical endpoints (cholinesterase inhibition); therefore, the MOEs were combined to identify a total intermediate-term MOE. However, since the dermal and inhalation target MOEs are different (100 and 300, respectively), an ARI was calculated in place of a total MOE. **To be acceptable, an ARI must be equal to, or greater than, one.** For the scenarios where there was no inhalation data, and thus dermal and inhalation MOEs were not aggregated, the target MOE remains 100. Chronic endpoints were not selected because coumaphos may not be considered to have exposures of chronic durations.

Baseline Level

All calculated short-term ARIs are a risk of concern (ARIs < 1) **at the baseline level** (long pants, long-sleeved shirt, no gloves, open mixing/loading) for all exposure scenarios **except** for the following:

- (1a) Mixing/loading liquids for high pressure hand wand at the application rate for swine of 5 lbs. ai per 1000 gallons and use rate of 100 gallons per day.

- (1d) Mixing/loading liquids for back oiler/rubbers.

- (3) Applying liquids for high pressure hand wands at the application rate for swine of 5 lbs. ai per 1000 gallons and use rate of 100 gallons per day.

The calculations of short-term dermal only risk (for scenarios lacking inhalation data) indicate a risk of concern (MOE < 100) **at the baseline level** for all exposure scenarios.

All calculated intermediate-term ARIs are a risk of concern (ARIs < 1) **at the baseline level** for all exposure scenarios.

Additional PPE

The calculations of short-term total risk indicate that the ARIs are not a risk of concern (ARIs > 1) **at the additional PPE level** (double layer of clothing, coveralls, chemical resistant apron, and chemical resistant gloves) for all exposure scenarios except for the following:

- (3) Applying liquids for high pressure hand wand at the application rate for cattle and horses at the use rate of 1,000 gallons/day (cannot be mitigated with engineering controls).

The calculations of short-term dermal only risk (for scenarios lacking inhalation data) indicate no risk of concern (MOEs > 100) **at the additional PPE level** for all exposure scenarios except for the following:

- (4) Applying dusts with a shaker can on cattle, horses, and swine bedding (cannot be mitigated

with engineering controls).

- (6) Loading/applying dusts with a mechanical duster on cattle, horses, and swine bedding (cannot be mitigated with engineering controls).

All calculated intermediate-term ARIs were more than 1 at the additional PPE level for all exposure scenarios except for the following:

- (1c) Mixing/loading for swim type dip vats.

Engineering Controls

The calculations of short-term total risk indicate that the ARIs are more than 1 at the engineering control level for all exposure scenarios.

All calculated intermediate-term ARIs indicate no risk of concern (ARIs > 1) at the engineering control level for all assessed exposure scenarios.

In summary, the following three exposure scenarios are above the Agency's level of concern at the highest level of risk mitigation: (3) applying liquids for high pressure hand wand at the application rate for cattle and horses at the use rate of 1,000 gallons/day; (4) applying dusts with a shaker can on cattle, horses, and swine bedding; and (6) loading/applying dusts with a mechanical duster on cattle, horses, and swine bedding.

6.0 Deficiencies/Data Needs

There were no available data to assess exposure to the following exposure scenarios: loading dusts into bags; inhalation exposure from applying dusts with a shaker can; and inhalation exposure from loading/applying dusts with a mechanical duster.

7.0 Cumulative Risk

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, coumaphos and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

Attachments:

Revised Occupational Exposure and Risk Assessment Updating the Coumaphos RED Published August, 1996. R. Sandvig memo, 12/28/99.

Revised Acute and Chronic Dietary Exposure and Risk Analysis for Coumaphos. C. Jarvis and S. Mason memo, 1/13/00.